REMARKS

Upon entry of this amendment, Claims 1-10 and 12-17 will be pending in the application.

The specification is being amended to correct a typographical error. Claim 1 is being amended to correct a typographical error in line 1. Claim 6 is being amended to insert the antecedent claim from which it depends. New claims 14-17 are being added, support being found, for example, on specification p. 6, lines 18-19 and in the working examples. No new matter is being added.

Applicants note that a Supplemental Information Disclosure Statement will be filed shortly, after reference copies are obtained. Consideration of this Supplemental Statement is respectfully requested before the next Office Action.

Claim rejections under 35 USC 102

Claims 1-10 and 12-13 are rejected under 35 USC 102(a) as being allegedly anticipated by WO02/08224. The Examiner posits that the reference teaches compounds such as its Example 20, said by the Examiner to anticipate the instant claims.

Applicants respectfully traverse. In the present claims, in the compounds of Formula (I) the Group R^3 is either trifluoromethyl, oxo, fluorine or an optionally substituted amino (see claim 1). WO02/08224 does not teach or suggest such compounds. Accordingly, the reference does not anticipate the present claims. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim rejections based on Double Patenting

Claims 1-10 and 12-13 are said by the Examiner to conflict with: Claims 1, 2, and 11-19 of 10/031844; Claims 14-23, 25 and 26 of 10/333829; and Claims 1-10, 13 and 16 of 10/466394. The Examiner requires Applicant to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the application (referencing 37 CFR 1.78(b) and MPEP 822).

Applicants respectfully traverse. As will be shown below, the present claims recite an R^3 moiety distinct from those claimed in the cited applications, such that the claims do not conflict.

The present application:

The present application has an international filing date of Jan 27, 2003 and a US national filing date of Jul 22, 2004. In the present claims:

- R^3 is in the 2-, 3- or 4-position and is trifluoromethyl; or
- R^3 is in the 2-position and is oxo; or
- R^3 is in the 3-position and is fluorine or amino; wherein the amino group is optionally substituted as set forth in the claims.

In addition, in the present claims when R^3 is disubstituted with a hydroxy or amino containing substituent and a carboxy containing substituent, these may together form a cyclic ester or amide linkage, respectively. Also, where one of R^3 and R^6, R^7, R^8 or R^9 contains a carboxy group and the other contains a hydroxy or amino group they may together form a cyclic ester or amide linkage.
(See current claim 1).

10/031844 (Attorney Docket P32372):

The '844 application has an international filing date of Jul 17, 2000 and a US national filing date of Jan 23, 2002. In the '844 claims:
R^3 is hydrogen; or
R^3 is in the 2-, 3- or 4-position and is:
carboxy; (C_{1-6})alkoxycarbonyl; aminocarbonyl, wherein the amino group is optionally substituted by hydroxy, (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkylsulphonyl, trifluoromethylsulphonyl, (C_{1-6})alkenylsulphonyl, (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl or (C_{2-6})alkenylcarbonyl and optionally further substituted by (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl or (C_{2-6})alkenyl; cyano; tetrazolyl; 2-oxo-oxazolidinyl optionally substituted by R^{10}; 3-hydroxy-3-cyclobutene-1,2-dione-4-yl; 2,4-thiazolidinedione-5-yl; tetrazol-5-ylaminocarbonyl; 1,2,4-triazol-5-yl optionally substituted by R^{10}; or 5-oxo-1,2,4-oxadiazol-3-yl; or
(C_{1-4})alkyl optionally substituted or ethenyl substituted with any of the substituents listed above for R^3 and up to 3 groups for R^{12} independently selected from:

thiol; halogen; (C_{1-6})alkylthio; trifluoromethyl; azido; (C_{1-6})alkoxycarbonyl; (C_{1-6})alkylcarbonyl; (C_{2-6})alkenyloxycarbonyl; (C_{2-6})alkenylcarbonyl; hydroxy optionally substituted by (C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl, (C_{2-6})alkenylcarbonyl or aminocarbonyl, wherein the amino group is optionally substituted by (C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkylcarbonyl or (C_{2-6})alkenylcarbonyl; amino optionally mono- or disubstituted by (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl, (C_{2-6})alkenylcarbonyl, (C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkylsulphonyl, (C_{2-6})alkenylsulphonyl or aminocarbonyl, wherein the amino group is optionally substituted by (C_{1-6})alkyl or (C_{2-6})alkenyl; aminocarbonyl, wherein the amino group is optionally substituted by (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl or $(C_{2-}$

$_6$)alkenylcarbonyl and optionally further substituted by (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl or (C_{2-6})alkenyl; oxo; (C_{1-6})alkylsulphonyl; (C_{2-6})alkenylsulphonyl; or (C_{1-6})aminosulphonyl, wherein the amino group is optionally substituted by (C_{1-6})alkyl or (C_{2-6})alkenyl;
in addition when R^3 is disubstituted with a hydroxy or amino containing substituent and carboxy containing substituent these may together form a cyclic ester or amide linkage, respectively; or
when R^3 is in the 3- or 4-position it may with R^2 or R^4 form a C_{3-5} alkylene group optionally substituted by a group R^5 selected from:
(C_{1-12})alkyl; hydroxy(C_{1-12})alkyl; (C_{1-12})alkoxy(C_{1-12})alkyl; (C_{1-12})alkanoyloxy(C_{1-12})alkyl; (C_{3-6})cycloalkyl; hydroxy(C_{3-6})cycloalkyl; (C_{1-12})alkoxy(C_{3-6})cycloalkyl; (C_{1-12})alkanoyloxy(C_{3-6})cycloalkyl; (C_{3-6})cycloalkyl(C_{1-12})alkyl; hydroxy-, (C_{1-12})alkoxy- or (C_{1-12})alkanoyloxy-(C_{3-6})cycloalkyl(C_{1-12})alkyl; cyano; cyano(C_{1-12})alkyl; (C_{2-12})alkenyl; (C_{2-12})alkynyl; tetrahydrofuryl; mono- or di-(C_{1-12})alkylamino(C_{1-12})alkyl; acylamino(C_{1-12})alkyl; (C_{1-12})alkyl- or acyl-aminocarbonyl(C_{1-12})alkyl; mono- or di- (C_{1-12})alkylamino(hydroxy) (C_{1-12})alkyl; optionally substituted phenyl(C_{1-12})alkyl, phenoxy(C_{1-12})alkyl or phenyl(hydroxy)(C_{1-12})alkyl; optionally substituted diphenyl(C_{1-12})alkyl; optionally substituted phenyl(C_{2-12})alkenyl; optionally substituted benzoyl or benzoyl(C_{1-12})alkyl; optionally substituted heteroaryl(C_{1-12})alkyl; and optionally substituted heteroaroyl or heteroaroyl(C_{1-12})alkyl;

wherein phenyl, benzoyl, heteroaryl and heteroaroyl groups are optionally substituted with up to five groups selected from halogen, mercapto, (C_{1-6})alkyl, phenyl, (C_{1-6})alkoxy, hydroxy(C_{1-6})alkyl, mercapto (C_{1-6})alkyl, halo(C_{1-6})alkyl, hydroxy, optionally substituted amino, nitro, carboxy, (C_{1-6})alkylcarbonyloxy, (C_{1-6})alkoxycarbonyl, formyl, and (C_{1-6})alkylcarbonyl groups.
(See current claim 1 as amended Aug 1, 2005, allowed).

Applicants also inform the Examiner of copending application no. 11/292,011, filed Dec 1, 2005, which is a divisional of the '844 application.

10/333829 (Attorney Docket P32623):

The '829 application has an international filing date of Jul 25, 2001 and a US national filing date of Jan 23, 2003. In the '829 claims:

R^3 is hydrogen; or
R^3 is in the 2-, 3- or 4-position and is:
carboxy; (C_{1-6})alkoxycarbonyl; aminocarbonyl, wherein the amino group is optionally substituted by hydroxy, (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkylsulphonyl, trifluoromethylsulphonyl, (C_{2-6})alkenylsulphonyl, (C_{1-}

$_{6}$)alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl or (C_{2-6})alkenylcarbonyl and optionally further substituted by (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl or (C_{2-6})alkenyl; cyano; tetrazolyl; 2-oxo-oxazolidinyl optionally substituted by R^{10}; 3-hydroxy-3-cyclobutene-1,2-dione-4-yl; 2,4-thiazolidinedione-5-yl; tetrazol-5-ylaminocarbonyl; 1,2,4-triazol-5-yl optionally substituted by R^{10}; or 5-oxo-1,2,4-oxadiazol-3-yl; or

(C_{1-4})alkyl or ethenyl optionally substituted with any of the substituents listed above for R^3 and/or 0 to 2 groups R^{12} independently selected from:

halogen; (C_{1-6})alkylthio; trifluoromethyl; (C_{1-6})alkoxycarbonyl; (C_{1-6})alkylcarbonyl; (C_{2-6})alkenyloxycarbonyl; (C_{2-6})alkenylcarbonyl; hydroxy optionally substituted by (C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl, (C_{2-6})alkenylcarbonyl or aminocarbonyl, wherein the amino group is optionally substituted by (C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkylcarbonyl or (C_{2-6})alkenylcarbonyl; amino optionally mono- or disubstituted by (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl, (C_{2-6})alkenylcarbonyl, (C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkylsulphonyl, (C_{2-6})alkenylsulphonyl or aminocarbonyl, wherein the amino group is optionally substituted by (C_{1-6})alkyl or (C_{2-6})alkenyl; aminocarbonyl, wherein the amino group is optionally substituted by (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl or (C_{2-6})alkenylcarbonyl and optionally further substituted by (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl or (C_{2-6})alkenyl; oxo; (C_{1-6})alkylsulphonyl; (C_{2-6})alkenylsulphonyl; or (C_{1-6})aminosulphonyl, wherein the amino group is optionally substituted by (C_{1-6})alkyl or (C_{2-6})alkenyl; or when R^3 is in the 3-position, hydroxy optionally substituted as described above;

in addition when R^3 is disubstituted with a hydroxy or amino containing substituent and carboxy containing substituent these may together form a cyclic ester or amide linkage, respectively.

Also, where one of R^3 and R^6, R^7, R^8 or R^9 contains a carboxy group and the other contains a amino group they may together form a cyclic ester or amide linkage.

(See current claim 14 as amended Mar 3, 2005, allowed).

10/466394 (Attorney Docket P32753):

The '394 application has an international filing date of Jan 22, 2002 and a US national filing date of Jan 26, 2004. In the '394 claims:

R^3 is hydrogen; or

R^3 is in the 2-, 3- or 4-position and is:

carboxy; (C_{1-6})alkoxycarbonyl; (C_{2-6})alkenyloxycarbonyl; aminocarbonyl wherein the amino group is optionally substituted by hydroxy, (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl,

aminocarbonyl(C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkylsulphonyl, trifluoromethylsulphonyl, (C_{2-6})alkenylsulphonyl, (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl or (C_{2-6})alkenylcarbonyl and optionally further substituted by (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl or (C_{2-6})alkenyl; cyano; tetrazolyl; 2-oxo-oxazolidinyl optionally substituted by R^{10}; 3-hydroxy-3-cyclobutene-1,2-dione-4-yl; 2,4-thiazolidinedione-5-yl; tetrazol-5-ylaminocarbonyl; 1,2,4-triazol-5-yl optionally substituted by R^{10}; or 5-oxo-1,2,4-oxadiazol-3-yl; or

(C_{1-4})alkyl or ethenyl optionally substituted with any of the substituents listed above for R^3 and/or 0 to 2 groups R^{12} independently selected from:

halogen; (C_{1-6})alkylthio; trifluoromethyl; (C_{1-6})alkoxycarbonyl; (C_{1-6})alkylcarbonyl; (C_{2-6})alkenyloxycarbonyl; (C_{2-6})alkenylcarbonyl; hydroxy optionally substituted by (C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl, (C_{2-6})alkenylcarbonyl or aminocarbonyl wherein the amino group is optionally substituted by (C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkylcarbonyl or (C_{2-6})alkenylcarbonyl; amino optionally mono- or disubstituted by (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl, (C_{2-6})alkenylcarbonyl, (C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkylsulphonyl, (C_{2-6})alkenylsulphonyl or aminocarbonyl wherein the amino group is optionally substituted by (C_{1-6})alkyl or (C_{2-6})alkenyl; aminocarbonyl wherein the amino group is optionally substituted by (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl or (C_{2-6})alkenylcarbonyl and optionally further substituted by (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl or (C_{2-6})alkenyl; oxo; (C_{1-6})alkylsulphonyl; (C_{2-6})alkenylsulphonyl; or (C_{1-6})aminosulphonyl wherein the amino group is optionally substituted by (C_{1-6})alkyl or (C_{2-6})alkenyl; or when R^3 is in the 3-position, hydroxy optionally substituted as described above;

in addition when R^3 is disubstituted with a hydroxy or amino containing substituent and carboxy containing substituent these may together form a cyclic ester or amide linkage, respectively.

Also, where one of R^3 and R^6 and R^7 contains a carboxy group and the other contains a hydroxyl or amino group they may together form a cyclic ester or amide linkage.

(See current claim 1, as of Jul 16, 2003 Preliminary Amendment).

As shown above, the present claims recite an R^3 moiety distinct from those claimed in the cited applications. The present claims therefore do not conflict with those of the cited applications. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim rejections under 35 USC 112

Claims 1-10 and 12-13 are rejected under 35 USC 112, 1st paragraph, as allegedly failing to comply with the enablement requirement. The Examiner asserts that the specification enables compounds and use to treat bacterial infections in mammals wherein R^4 is benzothiadiazole. The Examiner asserts that only R^4 being benzothiadiazole has been made, taught or enabled by the instant specification, and that no other heterocyclic or carbocyclic rings have been suggested or enabled by the instant specification. Applicants respectfully traverse.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. See, e.g., *United States v. Telectronics, Inc.,* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). See also *In re Wands,* 858 F.2d at 737, 8USPQ2d at 1404 (Fed. Cir. 1988). A patent need not teach, and preferably omits, what is well known in the art. See, e.g., *In re Buchner,* 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Further, the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright,* 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). See also MPEP 2164.01, pp. 2100-197 to 2100-198, Rev. 3, Aug 2005.

In the instant Office Action, the Examiner has put forth two bases for the rejection. The Examiner bases the rejection in part on the position that no other heterocyclic or carbocyclic rings have been suggested or enabled by the instant specification. Applicants respectfully disagree. Clearly Applicants teach that the group R^4 (which comprises the group R^5), comprises an optionally substituted bicyclic carbocyclic or heterocyclic ring system (A) (see, e.g., p. 3, line 9 – p. 4, line 7). In addition, Applicants disclose numerous examples of ring systems (A) as well as preferred R^5 groups (see, e.g., p. 6, line 29 – p. 8, line 5).

Furthermore, Applicants provide a detailed disclosure of how to prepare such compounds (see, e.g., p. 11, line 23 - p. 29, line 23, and working examples on p. 32 – p. 39). Applicants also disclose how to use the compounds of the invention (see, e.g., p. 29, line 33 – p. 31, line 27).

Examples from the chemical literature also support the scope of the present claims. For example, antibacterial, structurally non-identical chemical compounds with attached

chemical substituent groups of similar scope to those of the present invention are exemplified in WO 02/08224, which is relied on by the Examiner in the instant Office Action.

WO 02/08224 discloses, for example, compounds of a formula (I) which may be substituted with the following variety of substituent groups at the same position corresponding to the variable R^4 substituent of formula (I) in the present invention:

> 1H-pyrrolo[2,3-b]-pyridin-2-yl, 1H-pyrrolo[3,2-b]-pyridin-2-yl, 3H-imidazo[4,5-b]-pyrid-2-yl, 3H-quinazolin-4-one-2-yl, benzimidazol-2-yl, benzo[1,2,3]-thiadiazol-5-yl, benzo[1,2,5]-oxadiazol-5-yl, benzofur-2-yl, benzothiazol-2-yl, benzo[b]thiophen-2-yl, benzoxazol-2-yl, chromen-4-one-3-I, imidazo[1,2-a]pyridin-2-yl, imidazo-[1,2-a]-pyrimidin-2-yl, indol-2-yl, indol-6-yl, isoquinolin-3-yl, [1,8]-naphthyridine-3-yl, oxazolo[4,5-b]-pyridin-2-yl, quinolin-2-yl, quinolin-3-yl, quinoxalin-2-yl, indan-2-yl, naphthalen-2-yl, 1,3-dioxo-isoindol-2yl, benzimidazol-2-yl, benzothiophen-2-yl, 1H-benzotriazol-5-yl, 1H-indol-5-yl, 3H-benzooxazol-2-one-6-yl, 3H-benzooxazol-2-thione-6-yl, 3H-benzothiazol-2-one-5-yl, 3H-quinazolin-4-one-2-yl, 3H-quinazolin-4-one-6-yl, 4-oxo-4H-pyrido[1,2-a]pyrimidin-3-yl, benzo[1,2,3]thiadiazol-6-yl, benzo[1,2,5]thiadiazol-5-yl, benzo[1,4]oxazin-2-one-3-yl, benzothiazol-5-yl, benzothiazol-6-yl, cinnolin-3-yl, imidazo[1,2-a]pyridazin-2-yl, imidazo[1,2-b]pyridazin-2-yl, pyrazolo[1,5-a]pyrazin-2-yl, pyrazolo[1,5-a]pyridin-2-yl, pyrazolo[1,5-a]pyrimidin-6-yl, pyrazolo[5,1-c][1,2,4]triazin-3-yl, pyrido[1,2-a]pyrimdin-4-one-2-yl, pyrido[1,2-a]pyrimidin-4-one-3-yl, quinazolin-2-yl, quinoxalin-6-yl, thiazolo[3,2-a]pyrimidin-5-one-7-yl, thiazolo[5,4-b]pyridin-2-yl, thiazolo[5,4-b]pyridin-6-yl, thieno[3,2-b]pyridin-6-yl, 2H-isoquinolin-1-one-3-yl, (2S)-2,3-dihydro-1H-indol-2-yl, (2S)-2,3-dihydro-benzo[1,4]dioxine-2-yl, 3-(R,S)-3,4-dihydro-2H-benzo[1,4]thiazin-3-yl, 3-(R)-(2,3-dihydro-[1,4]dioxino[2,3-b]pyridin-3-yl, 2,3-dihydro-[1,4]dioxino[2,3-b]pyridin-3-yl, and 3-substituted-3H-quinazolin-4-one-2-yl.

See, for example, WO 02/08224 pp. 7-8 and the numerous working examples on pp. 29-66, which exemplify a diversity of R^4 groups. As shown by the MIC data on p. 66, many of these examples exhibited anti-bacterial activity. One having ordinary skill in the art would consider the R^4 groups disclosed in WO 02/08224 to be suitable R^4 groups in the present invention.

The Examiner also bases the rejection on Applicants' working examples, which exemplify compounds having a benzothiadiazole R^4 group. However, it is well known that the first paragraph of 35 USC 112 does not require specific exemplification of all of the subject matter falling within the scope of a broad claim term. See *In re Robins,* 166 USPQ 552, 555 (CCPA 1970); *In re Borkowski,* 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA

1970). The claims should not be limited to the compounds specifically exemplified in the specification when, as here, there is a clear disclosure of a broad genus.

Applicants respectfully submit that the Office has failed to meet its initial burden to establish a reasonable basis to question the enablement of the present claims. Furthermore, Applicants have rebutted the only bases set forth by the Office for the rejection. Applicants respectfully submit that one reasonably skilled in the art could make and use the claimed invention without undue experimentation, and that the scope of enablement bears a reasonable correlation to the scope of the claims. In view of all of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

In view of the above comments, Applicants believe that the present claims are in condition for allowance and earnestly solicit the same.

Should the Examiner have any questions or otherwise wish to discuss any aspect of this case, the Examiner is encouraged to contact the undersigned attorney at the number listed below.

Respectfully submitted,

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